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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,457	02/21/2002	Anne M. Pianca	98P1021US08	3029

7590 11/08/2002

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EXAMINER
EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 11/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,457	PIANCA ET AL.	
	Examiner	Art Unit	
	Georg R Evanisko	3762	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 6, 9, 11, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain et al, 5925073, in view of Swoyer, 5683445. Since a guidewire is used in Chastain through the lumen, it is inherent that there be a distal opening in the lead (in the alternative, see the 103 rejection below).

Chastain discloses the claimed invention and providing an anchor in the coronary sinus to stabilize the electrode, but does not teach having a tip electrode and canted portion that orients the tip electrode toward the vessel wall. Swoyer teaches that it is known to have a coronary sinus anchor lead have a tip electrode and canted portion that orients the tip electrode toward the

vessel wall to provide effective stimulation of the heart. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coronary sinus anchor lead as taught by Chastain, with a tip electrode and canted portion that orients the tip electrode toward the vessel wall as taught by Swoyer, since such a modification would provide a coronary sinus anchor lead with a tip electrode and canted portion that orients the tip electrode toward the vessel wall to provide effective stimulation of the heart.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain et al in view of Swoyer.

Chastain in view of Swoyer discloses the claimed invention except for the ring electrode located on, before, or after the bends. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the anchoring lead as taught by Chastain in view of Swoyer, with the use of a ring electrode on, before or after the bends since it was known in the art that ring electrodes are included anywhere on leads to provide bipolar sensing and pacing or additional sensing and pacing.

Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain et al in view of Swoyer as applied to claims 6 and 1 above.

Chastain in view of Swoyer discloses the claimed invention except for the humps being in different geometric planes. It would have been an obvious matter of design choice to one skilled in the art to modify the anchoring lead as taught by Chastain in view of Swoyer with the humps in the anchor being located in different geometric planes, since applicant has not disclosed that providing the humps in different geometric planes provides any criticality and/or

unexpected results and it appears that the invention would perform equally well with any location of the humps, such as the humps being located in the same plane as taught by Chastain in view of Swoyer to anchor the lead in the coronary sinus.

Claims 3, 7, 8, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain in view of Swoyer as applied to claims 2, 6, and 1 above.

Chastain in view of Swoyer discloses the claimed invention except for the lead having a distal opening to receive a guidewire, the stylet having a tapered portion, the first and second bend located in the range of 0.15-0.7 inches from the distal end and first bend, and the lead having a textured region of ePTFE or porous material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical electrical lead as taught by Chastain in view of Swoyer with the lead having a distal opening to receive a guidewire, the stylet having a tapered portion, and the lead having a textured region of ePTFE or porous material (such as silicone rubber, polyurethane, or ceramic) since it was known in the art that medical electrical leads have a distal opening to receive a guidewire to allow the lead to be positioned in the body, that leads use a stylet with a tapered portion to allow the stylet to fit in the narrow distal end of the lead and to position the lead, and that leads have a textured region of ePTFE or porous material to allow the lead to anchor in the body.

In addition, it would have been an obvious matter of design choice to one skilled in the art to modify the medical electrical lead as taught by Chastain in view of Swoyer to include ePTFE as the textured region and the first and second bends being located 0.15-0.7 inches from the distal end and first bend, since applicant has not disclosed that ePTFE and the first and

second bends being located 0.15-0.7 inches from the distal end and first bend provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any biocompatible textured material or any location of the bends, such as silicone rubber, polyurethane or ceramic for allowing the lead to anchor in the body as taught by Chastain in view of Swoyer and in view of one having ordinary skill in the art for allowing the lead to anchor in the coronary sinus or such as the S-shaped or zig-zag shaped lead location of the bends as taught by Chastain in view of Swoyer to allow the lead to anchor in the coronary sinus.

Claims 1, 2, and 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swoyer in view of Chastain et al (5925073).

Swoyer discloses the claimed invention to anchor a lead in the coronary sinus except for the lead having an s-shape with a plurality of bends for the anchoring. Chastain teaches that it is known to use an s-shaped lead with a plurality of bends to anchor a lead in the coronary sinus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Swoyer, with the s-shaped lead with a plurality of bends as taught by Chastain, since such a modification would provide a lead with an s-shape with a plurality of bends to anchor a lead in the coronary sinus.

In the alternative, it would have been an obvious matter of design choice to one skilled in the art to modify the anchoring lead as taught by Swoyer with the use of an s-shape anchor with a plurality of bends, since applicant has not disclosed that the s-shape with a plurality of bends provides any criticality and/or unexpected results and it appears that the invention would perform

equally well with any shape that was non-helical, such as the J-shape or C-shape as taught by Swoyer for anchoring the lead in the coronary sinus.

Response to Arguments

Applicant's arguments filed 10/04/02 have been fully considered but they are not persuasive. The argument that as "described by Chastain...the wave shapes of the lead absorbs heart and respiratory motion forces, 'thereby decoupling the mechanisms of dislodgement from the distal end or the lead' and thus Chastain et al. specifically teach that the distal end of the lead is decoupled from the heart tissue to prevent dislodgment" is not persuasive since Chastain's "decoupling" is not discussing decoupling the electrode from heart tissue but of decoupling the heart motions from the lead to prevent dislodgement of the lead and stability of the electrode. Several examples of this are seen in Chastain, such as in the abstract "the lead body exhibits a two-dimensional wave...to stabilize the electrode against displacement", in col 1, line 51, "a means must be provided to decouple the relative motion of the heart from the distal tip of the lead" and in col 3, line 40, "while other bends...function to decouple movements of the lead body from displacing the electrode from its desired stimulating site". In all cases, including the argument presented by the applicant, Chastain's decoupling is directed to decoupling the heart motions from the lead to prevent lead dislodgement and stability of the electrode. In addition, Chastain does not contain any statements teaching that the electrode should be decoupled from the heart tissue, but states in the background, col 1, that it is known to have electrodes in contact with endocardial tissue (line 18) and on the surface of the left ventricle when advanced through the coronary sinus (line 39).

The argument on page 5 that the examiner contends that claims 1, 2, and 4-13 are obvious over Swoyer alone is not persuasive since this rejection was not presented in the previous action. In addition, the argument that the claimed lead will "also engage diametrically opposed sides of the vessel" and that Swoyer does not teach this is not persuasive since the claims do not contain a limitation directed to engaging diametrically opposed sides of the vessel.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone numbers for the

organization where this application or proceeding is assigned are 703 306-4520 for regular communications and 703 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

George R Evanisko
Primary Examiner
Art Unit 3762
11/7/2

GRE
November 7, 2002